Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0969151	02/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Wasatch Pediatrics - Draper Office	114 E 12450 S Ste 100, Draper, UT	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on quality control record review, procedure manual review and interview with staff, the laboratory failed to include the process used to determine the acceptable range for total bilirubin quality control at the neonatal test range in the procedure for total bilirubin control performance. The laboratory performed approximately 0 to 2 bilirubin test assays per day. Findings include: 1. The laboratory quality control records for total bilirubin testing included documentation the control reagent did not include an assayed value established for the Piccolo instrument in use for neonatal total bilirubin. 2. The laboratory procedure manual for total bilirubin assay testing did

	not include the process used by the laboratory to establish control acceptable ranges. 3. In an interview conducted on 02/02/2018 at approximately 3:00 P.M. staff stated the total bilirubin procedure did not include a description for how the laboratory determined the acceptable range for control materials that did not include the acceptable range for testing performed on the Piccolo instrument.